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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,978	06/26/2003	John D. Dobak III	103002	6407
7590 11/04/2008 MAYER FORTKORT & WILLIAMS 251 NORTH AVENUE WEST 2ND FLOOR WESTFIELD, NJ 07090			EXAMINER JOHNSON III, HENRY M	
			ART UNIT 3769	PAPER NUMBER
			MAIL DATE 11/04/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/608,978

Applicant(s)

DOBAK ET AL.

Examiner

HENRY M. JOHNSON III

Art Unit

3769

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 6-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 6-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Response to Arguments

Applicant's arguments filed August 27, 2008 have been fully considered, but are moot in view of the new grounds of rejection. The examiner takes the position that the prior art previously cited renders the key features of the catheter unpatentable and that the use of struts to maintain coaxial lumens positioned properly is well known in the art as evidenced by patents to Diederich and Jasso, which have been included in new 35 U.S.C. 103 rejections.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,968,069 to Dusbabek et al. in view of U.S. Patent 4,445,892 to Hussein et al. and U.S. Patent 5,620,479 to Diederich and U.S. Patent 4,413,636 to Jasso. Dusbabek et al. disclose a catheter with inner and outer balloons at a distal end (Fig. 11, #s 14 & 50) arranged with inner and outer tube structures. Both balloons are attached to the distal most portion of the inner tube and the proximal portion of the inner balloon also attached to the inner tube. The proximal

portion of the outer tube is attached to the outer tube. Volumes are disclosed between the inner balloon and the inner tube and between the dual balloons. Lumens are provided communicate with interior volumes and a central lumen which is interpreted as capable of use with a guidewire. Dusbabek et al. teach the use of marker bands (Col. 9, line 43). Dusbabek et al. do not disclose the use of spacers in the structure. Hussein et al. disclose a dual balloon catheter (abstract) with inner and outer tubes wherein spacers are provided to center the inner tube within the outer tube and allow fluid flow around the inner tube (Fig 6, #s 308 & 310). Hussein et al. teach the use of perfluorocarbon for cooling. Diederich and Jasso both teach the use of structures to maintain an inner tube centered within an outer tube that allow fluid flow between the tubes. It would have been obvious to one skilled in the art to use spacers as taught by Hussein et al./ Diederich/Jasso in the invention of Dusbabek et al. to maintain alignment of concentric tubes.

Claims 2-4 and 7-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,968,069 to Dusbabek et al. in view of U.S. Patent 4,445,892 to Hussein et al. and U.S. Patent 5,620,479 to Diederich and U.S. Patent 4,413,636 to Jasso as applied to claim 1 above and further in view of U.S. Patent 5,106,360 to Ishiwara et al. Dusbabek et al., Hussein et al., Diederich and Jasso are discussed above, but do not teach separate supply and return lumens. Ishiwara et al. teach a catheter device with concentric balloons defining a volume between an inner and outer balloon and between the inner balloon and a tube with multiple lumens (Fig. 5) in fluid connection with the volumes (Fig. 5, # 30). Each volume is provided with two lumens as is common for the circulation of a cooling fluid or refrigerant. Catheters with multiple lumens for various purposes are well known and it would have been obvious to one skilled in the art to combine the teachings of Dusbabek et al., Ishiwara et al., Hussein et al., Diederich and Jasso to create a dual balloon catheter with cooling/heating capability as all teach features common in balloon catheters and a skilled artisan would look to such related art.

Regarding claims 10 and 11, the use of alternative cooling fluids is considered obvious to a skilled artisan.

If a person of ordinary skill can implement a predictable variation, §103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill. The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results. (See KSR [127 S Ct. at 1739]).

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,968,069 to Dusbabek et al. in view of U.S. Patent 4,445,892 to Hussein et al., and U.S. Patent 5,620,479 to Diederich and U.S. Patent 4,413,636 to Jasso in view of U.S. Patent 5,106,360 to Ishiwara et al. as applied to claim 8 above and further in view of U.S. Patent 6,063,101 to Jacobsen et al. Dusbabek et al., Ishiwara et al. and Hussein et al./Diederich/Jasso teach all of the limitations of the claim except a fluid contrast media. Jacobsen et al. teach that it is old and well known in the art to provide a contrast media as an inflation fluid for a balloon catheter. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a fluid contrast media in the invention of Dusbabek et al./Ishiwara et al./Hussein et al./Diederich/Jasso in the fluid for inflating the balloon.

Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,968,069 to Dusbabek et al. in view of U.S. Patent 4,445,892 to Hussein et al. and U.S. Patent 5,620,479 to Diederich and U.S. Patent 4,413,636 to Jasso in view of U.S. Patent 5,106,360 to Ishiwara et al. as applied to claim 8 above and further in view of U.S. Patent 6,497,721 to Ginsburg, et al. Dusbabek et al., Ishiwara et al. and Hussein et al./Diederich/Jasso are discussed above, but do not teach specific pumps for the fluid delivery. Ginsburg et al. disclose a similar device and teach that it is old and well known in the art to use a variety of

different pumps to circulate the heat exchange fluid (col. 24 lines 10-14). Each of the pumps disclosed by Ginsburg et al. may be substituted one for the other. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a gear pump for fluid delivery in the invention of Dusbabek et al./Ishiwara et al./Hussein et al./Diederich/Jasso particularly in view of the teaching of Ginsburg et al. that a substitution as such would be proper.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication should be directed to HENRY M. JOHNSON III at telephone number (571)272-4768.

/Henry M. Johnson, III/
Supervisory Patent Examiner, Art Unit
3769

/HMJ/
11/3/2008